

- (i) an anti-thyroglobulin antibody capable of binding to a first type of thyroglobulin and a second type of thyroglobulin,
- (ii) a specific lectin or a specific antibody capable of binding to a specific structure of a sugar chain of the first type of thyroglobulin but not capable of binding to the sugar chain of the second type of thyroglobulin;

(b) adding to the fluid sample said reagent; and

El (c)(i) measuring a total amount of conjugate formed in step (b) of the anti-thyroglobulin antibody with both of the first and second types of thyroglobulin; and

ul (ii) measuring an amount of conjugate formed in step (b) of said specific lectin or said specific antibody with the first type of thyroglobulin,

(2) determining the malignancy of the thyroid tumor by comparing a calculated ratio of the amount measured in (c)(ii) to the amount of total thyroglobulin measured in (c)(i) in the sample with a corresponding predetermined ratio from a reference fluid sample originating from a living body having a normal thyroid or a benign thyroid;

wherein the sample is determined to be malignant when the calculated ratio is significantly higher or lower than that of the reference fluid sample of the normal or benign thyroid.

59. (Amended) A method for determining malignancy of a thyroid tumor comprising:

52 (1) measuring an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the steps comprising:

(a) adding to the sample a specific lectin or a specific antibody capable of binding to a

specific structure of a sugar chain of a first type of thyroglobulin but not capable of binding to a sugar chain of a second type of thyroglobulin, to form a conjugate of the specific lectin or the specific antibody with the first type of thyroglobulin;

(b) separating said conjugate from the non-conjugated second type of thyroglobulin;

(c) measuring said conjugate content, for determining the amount of the first type of thyroglobulin; or

92
93
(d) measuring an amount of the non-conjugated second type of thyroglobulin,

(2) determining malignancy of the thyroid tumor by comparing a calculated ratio of the amount measured in (c) or (d) to an amount of total thyroglobulin in the sample with a corresponding predetermined ratio from a reference fluid sample originating from a living body having a normal thyroid or a benign thyroid;

wherein the sample is determined to be malignant when the calculated ratio is significantly higher or lower than that of the reference fluid sample of the normal or benign thyroid.

76. (Amended) The method of claims 51, 56, 59 and 68-75, wherein said specific antibody is one reactive with an Lewis type sugar chain.

93
77. (Amended) The method according to claims 51, 56, 59 and 68-75, wherein the sugar chain with the specific structure is one found in thyroglobulin which is produced by a carcinoma cell.
